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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,933	03/27/2007	Galit Levin	85189-13500	2953

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

DOUKAS, MARIA E

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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11/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,933	Applicant(s) LEVIN ET AL.	
	Examiner MARIA E. DOUKAS	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/28/2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 5-7, 9, 12-17, 19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines” to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).

In Reference to Claims 1, 14, and 24

Bramson teaches a system and method for intradermal delivery of an agent comprising: an apparatus for generating a plurality of micro-channels in the skin (Altea; p. 258, “Microporation” section) that comprises: an electrode cartridge comprising a plurality of electrodes (set of 80 μ m diameter tungsten wires strapped on edge of ceramic substrate) to be oriented generally perpendicularly to the skin (even though the tungsten wires are strapped around a ceramic substrate, they still have a perpendicular

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component to them due to the 80 micron diameter they possess. When the substrate with the tungsten wires is placed in the vicinity of the skin, the 80 micron diameter of the wire protrudes perpendicularly from the substrate towards the skin) ; and a main unit comprising a control unit (microprocessor control circuitry) which is adapted to apply electrical energy between two or more electrodes in the vicinity of the skin, enabling ablation of the stratum corneum (p. 259, col. 1, lines 3-9), thereby generating in the stratum corneum a plurality of micro-channels (Figure 1) having a diameter of about 10 microns to about 100 microns and a depth of about 20 microns to about 300 microns (p. 259, col. 1, lines 3-23, wherein the claimed diameter and depth of the micro-channels falls within the range taught by the prior art, and there is therefore no structural difference between that claimed and that taught by the prior art - see MPEP §2144.05). Bramson further teaches applying a vaccine via the use of a patch to the skin after the micro-channels are created (p. 259, col. 1, "Liquid reservoir patch"). Bramson fails to teach wherein a cosmetic or dermatological composition comprising a cosmetic agent and carrier devoid of permeation enhancers is applied to the skin after the micro-channels are created. Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one cosmetic agent and an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being an optional treatment method) and further teaches wherein the composition is contained within a patch reservoir that can be attached to the skin (col. 14, lines 20-23). Zhang teaches this patch reservoir composition in order to provide a

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means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the vaccine patch of Bramson to have the cosmetic composition as taught by Zhang instead of the vaccine and then use this patch to deliver the desired agents in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47). Since Bramson teaches applying a liquid reservoir patch after the micro-channels are created, one of ordinary skill in the art would be capable of modifying the type of liquid reservoir patch that is used to have one that contains a cosmetic composition depending on the intended use of the device.

In Reference to Claim 3

Bramson in view of Zhang teaches the device of claim 1 (see rejection of claim 1 above). Bramson further teaches wherein the electrode cartridge is removable as the user removes the electrode cartridge (set of tungsten wires) after creating the micro-channels.

In Reference to Claims 5-7 and 15-17

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above). Zhang further teaches wherein the cosmetic agent is selected from the claimed group (col. 7, lines 45-48). Since claims 5 and 15 list a Markoush

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grouping, claims 6, 16, 7, and 17 further specify the type of xanthine and type of hydroxy acid that can be chosen from the grouping, however ascorbic acid can still be chosen as the cosmetic agent from the claim group 5, thus meeting claims 6 and 7).

In Reference to Claims 9, 12, 13, 19, 22, and 23

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above). Zhang further teaches wherein the composition further comprises at least one of the claimed components (col. 1, line 40) and is in one of the claimed forms (col. 6, lines 53-57).

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over “Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines” to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2002/0010414 to Coston (Coston).

In Reference to Claim 4

Bramson in view of Zhang teaches the device of claim 1 (see rejection of claim 1 above). Bramson further teaches wherein the microporation parameters can be controlled by the user interface, but fails to explicitly teach wherein the electrical energy is of radio frequency. Coston teaches an apparatus that creates at least one micro-

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channel in the skin by applying electrical energy between two or more electrodes (paragraphs [0013-0015]) and teaches that the electrical energy used is of radio frequency (paragraph [0016], wherein the frequency of 30 Hz-10,000 kHz falls within the radio frequency range defined by webopedia.com to be “any frequency within the electromagnetic spectrum associated with radio wave propagation”). Although Bramson fails to explicitly teach the frequency parameter that is used to create the micro-channels, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the parameter to fall within the radio frequency range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable range involves only routine skill in the art. Further, since the radio frequency ranges for use to create micro-channels are well known in the art, as evidenced by Coston, one with ordinary skill would be capable of using the device of Bramson within this range.

4. Claims 8, 10, 11, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines” to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).as applied to claims 1, 5, 14, and 15 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley).

In Reference to Claims 8 and 18

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Bramson in view of Zhang teaches the device of claims 5 and 15 (see rejection of claims 5 and 15 above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley teaches delivery of cosmetic agents to the skin that can include hydroquinone (col. 4, lines 65-66) in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the cosmetic agent used in the patch of Bramson in view of Zhang to be hydroquinone as taught by Henley in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. Therefore, since the device of Bramson in view of Zhang is used for the treatment of skin conditions, and hydroquinone is well known in the art as a treatment of skin conditions, it is within the level of one of ordinary skill to use hydroquinone within the device.

In Reference to Claims 10, 11, 20, and 21

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above) but fails to teach wherein the composition further comprises an antibacterial agent. Henley teaches the delivery of antibacterial agents to the skin (col. 2, lines 9-11; col. 4, lines 49-50) in order to inhibit bacterial growth (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified composition used in the patch of Bramson in

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view of Zhang to comprise an antibacterial agent as taught by Henley in order to inhibit bacterial growth (Merriam-Webster definition). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Arguments

5. Applicant's arguments filed 6/25/2009 have been fully considered but they are not persuasive. Applicant argues that Bramson does not teach the claimed invention wherein the electrodes are perpendicular to the skin surface so that electrical energy is applied between the electrodes and is carried by electrical current to be converted within the skin to heat in order to ablate the stratum corneum and form micro-channels. This is not found persuasive because Bramson in view of Zhang does teach the claimed structural limitations set forth in claim 1 and method claim 14. Bramson teaches that the plurality of electrodes (tungsten wires) are oriented perpendicularly to the skin as even though the tungsten wires are strapped around a ceramic substrate, they still have a perpendicular component to them due to the 80 micron diameter they possess. When the substrate with the tungsten wires is placed in the vicinity of the skin, the 80 micron diameter of the wire protrudes perpendicularly from the substrate towards the skin. Furthermore, the argument that Bramson does not teach the control unit applying electrical energy *between* the wires is not found persuasive. The microporation tip of Bramson comprises resistive elements in the form of tungsten wires strapped over a ceramic substrate. The control circuitry passes electrical current through the wires,

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wherein the current passes through the entire array of the resistive elements in order to ablate the stratum corneum and form the desired micro-channels (p. 251, col. 2; p. 259, col. 1). The electrical current therefore moves between the electrodes (tungsten wires) to enable ablation of the stratum corneum. Further, the language recited in the claim stating "A control unit which is adapted to apply electrical energy..." is functional language, and, since the structure of the device of Bramson provides a control unit capable of applying electrical energy, there is no patentable distinction in structure between that claimed and that taught by the prior art – see MPEP §2111.04.

In regards to method claim 14, even if the structural limitations claimed were not met by the prior art, the combination of Bramson and Zhang still reads on the claimed method, as it has been held that to be entitled to weight in a method claim, the recited structure limitations therein must affect the method in a manipulative sense and not amount to the mere claiming of a use of a particular structure (*Ex parte Pfeiffer*, 1962 C.D. 408 (1961)). The structure claimed in method claim 14 does not affect the step of generating a plurality of micro-channels in an area of the skin of a subject in a manipulative sense, and therefore adds no patentable weight to the claim to make it patentable over the cited prior art.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767